108TH CONGRESS 1ST SESSION

H. R. 1032

To amend title XVIII of the Social Security Act to provide for special treatment for certain drugs and biologicals under the prospective payment system for hospital outpatient department services under the Medicare Program.

IN THE HOUSE OF REPRESENTATIVES

February 27, 2003

Mr. Shaw introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide for special treatment for certain drugs and biologicals under the prospective payment system for hospital outpatient department services under the Medicare Program.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 **SECTION 1. SHORT TITLE.**
- 4 This Act may be cited as the "Beneficiary Access to
- 5 Care Act of 2003".

| 1 | SEC. 2. TREATMENT OF DRUGS AND BIOLOGICALS UNDER |
|----|--|
| 2 | OUTPATIENT HOSPITAL PROSPECTIVE PAY- |
| 3 | MENT SYSTEM. |
| 4 | (a) Separate APCs for Most Drugs and |
| 5 | BIOLOGICALS.— |
| 6 | (1) In General.—Section 1833(t)(2) of the |
| 7 | Social Security Act (42 U.S.C. 1395l(t)(2) is amend- |
| 8 | ed— |
| 9 | (A) by striking "and" at the end of sub- |
| 10 | paragraph (F); |
| 11 | (B) striking the period at the end of sub- |
| 12 | paragraph (G) and inserting "; and"; and |
| 13 | (C) by adding at the end the following: |
| 14 | "(H) the Secretary shall treat as a sepa- |
| 15 | rate group of covered OPD services— |
| 16 | "(i) any drug or biological that was |
| 17 | treated as such a group as of December |
| 18 | 31, 2002; and |
| 19 | "(ii) any drug or biological that has |
| 20 | ceased to be eligible for transitional, pass- |
| 21 | through payments under paragraph (6) by |
| 22 | reason of the limited period of payment |
| 23 | specified in paragraph (6)(C)(i).". |
| 24 | (2) Effective date.—The amendments made |
| 25 | by paragraph (1) shall apply to items and services |
| 26 | furnished on or after January 1, 2004. |

| 1 | (b) Payment Rates for Non-Pass-Through |
|----|---|
| 2 | Drugs and Biologicals.— |
| 3 | (1) Program payments.—Section 1833(t) of |
| 4 | such Act (42 U.S.C. 1395l(t)) is amended— |
| 5 | (A) in paragraph (3), by amending sub- |
| 6 | paragraph (D) to read as follows: |
| 7 | "(D) CALCULATION OF MEDICARE OPD |
| 8 | FEE SCHEDULE AMOUNTS.— |
| 9 | "(i) In General.—The Secretary |
| 10 | shall compute a Medicare OPD fee sched- |
| 11 | ule amount for each covered OPD service |
| 12 | (or group of such services) furnished in a |
| 13 | year, in an amount that (except as pro- |
| 14 | vided in clause (ii)) is equal to the product |
| 15 | of— |
| 16 | "(I) the conversion factor com- |
| 17 | puted under subparagraph (C) for the |
| 18 | year, and |
| 19 | "(II) the relative payment weight |
| 20 | (determined under paragraph (2)(C) |
| 21 | or paragraph (9)(A)) for the service |
| 22 | or group. |
| 23 | "(ii) Special rules for 2004.— |
| 24 | "(I) IN GENERAL.—Notwith- |
| 25 | standing clause (i), the Medicare OPD |

| 1 | fee schedule amount for 2004 for a |
|----|--|
| 2 | drug or biological that is treated as a |
| 3 | separate group of covered OPD serv- |
| 4 | ices and is a single-source drug (as |
| 5 | defined in section $1927(k)(7)(A)(iv)$ |
| 6 | or an innovator multiple source drug |
| 7 | (as defined in section |
| 8 | 1927(k)(7)(A)(ii)) may not be less |
| 9 | than an amount equal to 83 percent |
| 10 | of the average wholesale price for the |
| 11 | drug or biological. |
| 12 | "(II) No revision of relative |
| 13 | PAYMENT WEIGHTS.—The relative |
| 14 | payment weights established under |
| 15 | paragraph (9)(A) for 2004 for groups |
| 16 | of covered OPD services other than |
| 17 | those to which subclause (I) applies |
| 18 | shall not be revised to take into ac- |
| 19 | count the application of such sub- |
| 20 | clause (I). |
| 21 | "(III) Definition.—For pur- |
| 22 | poses of subclause (I), the term 'mul- |
| 23 | tiple source drug or biological' has the |
| 24 | meaning given to the term 'multiple |

| 1 | source drug' in section |
|----|--|
| 2 | 1927(k)(7)(A)(i).''; |
| 3 | (B) in paragraph (4)— |
| 4 | (i) in subparagraph (A), by striking |
| 5 | "Secretary, as computed under paragraphs |
| 6 | (2)(D) and $(2)(E)$ " and inserting "Sec- |
| 7 | retary (as computed under paragraphs |
| 8 | (2)(D) and (2)(E)), except that the Medi- |
| 9 | care OPD fee schedule amount determined |
| 10 | under paragraph (3)(D) for a drug or bio- |
| 11 | logical that is treated as a separate group |
| 12 | of covered OPD services shall not be ad- |
| 13 | justed for relative differences in the cost of |
| 14 | labor''; and |
| 15 | (ii) in subparagraph (B), by striking |
| 16 | "adjusted"; and |
| 17 | (C) in paragraph (9), by adding at the end |
| 18 | the following: |
| 19 | "(D) USE OF EXTERNAL DATA.—In deter- |
| 20 | mining the relative payment weight for any |
| 21 | drug or biological that is treated as a separate |
| 22 | group of covered OPD services for any year |
| 23 | after 2003, the Secretary shall adjust the |
| 24 | weight otherwise determined under this para- |
| 25 | graph with respect to the drug or biological to |

1 the extent that reliable and valid data collected 2 and submitted by entities and organizations 3 other than the Department of Health and 4 Human Services (including data submitted in 5 public comments on the proposed rule promul-6 gated with respect to the system established 7 under this subsection for 2004) demonstrate 8 that such payment weight is inadequate or inac-9 curate. In the case of any adjustments made 10 pursuant to the preceding sentence for 2004, 11 the Secretary shall not revise the relative pay-12 ment weights for other groups of covered OPD 13 services for such year to take into account such 14 adjustments, and the medicare OPD fee sched-15 ule amount determined under paragraph (3)(D) 16 using a relative weight resulting from such an 17 adjustment shall be subject to the minimum 18 amount described in clause (ii)(I) of such para-19 graph.". 20 (2) Copayments.—Section 1833(t)(8)(E) of 21 such Act (42 U.S.C. 1395l(t)(8)(E)) is amended— 22

(A) in the heading, by striking "OUTLIER AND PASS-THROUGH" and inserting "CERTAIN"; and

23

24

| 1 | (B) by striking "paragraphs (5) and (6)" |
|----|---|
| 2 | and inserting "paragraphs (3)(D)(ii), (5), and |
| 3 | (6)". |
| 4 | (3) Exceptions to budget neutrality re- |
| 5 | QUIREMENT.—Section 1833(t)(9)(B) of such Act |
| 6 | (42 U.S.C. 1395l(t)(9)(B)) is amended by adding at |
| 7 | the end the following: "In determining the budget |
| 8 | neutrality adjustment required by the preceding sen- |
| 9 | tence, the Secretary shall not take into account— |
| 10 | "(i) any expenditures that would not |
| 11 | have been made but for the application of |
| 12 | clause (ii) of paragraph (3)(D); or |
| 13 | "(ii) any expenditures made by reason |
| 14 | of an adjustment required by subpara- |
| 15 | graph (D) for 2004.". |
| 16 | (c) Study of Pharmacy Services Used to Pro- |
| 17 | VIDE CANCER DRUG THERAPIES IN HOSPITAL OUT- |
| 18 | PATIENT SETTING.— |
| 19 | (1) In General.—The Comptroller General of |
| 20 | the United States shall conduct a study of payments |
| 21 | under part B of title XVIII of the Social Security |
| 22 | Act for pharmacy service costs and related costs that |
| 23 | are incurred in acquiring chemotherapy and sup- |
| 24 | portive care drugs and providing these therapies to |

| 1 | cancer patients in hospital outpatient departments. |
|----|---|
| 2 | The study shall— |
| 3 | (A) identify pharmacy costs, including the |
| 4 | costs of storage, handling, processing, quality |
| 5 | control, disposal, compliance with safety proto- |
| 6 | cols and regulations, establishing dosage regi- |
| 7 | mens that avoid drug interactions and contra- |
| 8 | indications, and pharmacy overhead; |
| 9 | (B) include a review of the adequacy of the |
| 10 | current payment methodology for pharmacy |
| 11 | service costs and related costs (including the |
| 12 | adequacy of the cost-to-charge ratios used in |
| 13 | such methodology); and |
| 14 | (C) identify any changes to that method- |
| 15 | ology that are necessary to ensure recognition |
| 16 | of, and appropriate payment for, all of the serv- |
| 17 | ices and functions inherent in the provision of |
| 18 | cancer treatment in hospital outpatient settings. |
| 19 | (2) Report to congress.—Not later than 12 |
| 20 | months after the date of enactment of this Act, the |
| 21 | Comptroller General shall submit to Congress a re- |
| 22 | port on the results of the study under paragraph |
| 23 | (1), including any recommendations for legislation |

- 1 necessary to implement the changes identified under
- 2 paragraph (1)(C).

 \bigcirc